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(54) Title: **APPARATUS FOR DISPENSING MEDICATION AND FOR PROVIDING INFORMATION THEREON**

(57) Abstract: The invention relates to an apparatus for dispensing medication and for providing information on the nature and the use thereof. The apparatus comprises container means suitable for receiving a medication package provided with medication; and dispensing means for releasing and dispensing medication from the container means. The apparatus is characterized in that the container means are further suitable for receiving an electronically readable carrier with information on the nature and the use of the medication, which carrier is included in the medication package, and that the apparatus is further provided with reading means for reading out information from this carrier. The apparatus may be provided with dispensing control means for controlling the dispensing means on the basis of the information on the carrier.

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Title: Apparatus for dispensing medication and for providing information thereon

The invention relates to an apparatus for dispensing medication and for providing information on the nature and the use thereof, comprising container means suitable for receiving a medication package provided with medication; and dispensing means for releasing and dispensing medication
5 from the container means.

Such an apparatus is known from Netherlands patent application NL 1008430. This document describes a dispenser with a clock adjustable by means of patient specific and product dependent information. The dispenser can register and fix the times at which a medication is taken from
10 the container and has provisions ensuring that a medication is dispensed in the right dose. The medication is placed in the dispenser, and the dispenser is to be adjusted to release the medication at the right times.

In practice, this manner of adjusting will be inconvenient. It can be expected that a large part of the user group will not be able to do the
15 adjustment perfectly. The risks involved are great; an incorrectly programmed or non-programmed dispenser will release the medication incorrectly or will not release it at all. Another drawback is that a package insert cannot be kept to the medication, so that during normal use the consultation thereof is actually not possible. For special situations, such as
20 skipping the taking of a medication or the loss thereof, this can give problems, because the view of the medication regimen is lost.

The object of the invention is to avoid the above-described drawbacks and to provide an apparatus for dispensing medication, which apparatus is arranged such that the adjustment thereof takes place substantially

automatically. A further object of the invention is to provide an apparatus which always gives a user all the information specifically applicable to him.

These objects are achieved by an apparatus according to the opening paragraph, in which the container means are further suitable for receiving
5 an electronically readable carrier with information on the nature and the use of the medication, which carrier is included in the medication package; and which apparatus is further provided with reading means for reading out information from this carrier. With an apparatus according to the
10 insertion of the medication package is accompanied with the insertion of the carrier adjusting the apparatus to effect dispensing in the proper manner.

In a preferred embodiment the apparatus is provided with dispensing control means which, on the basis of the electronic information from the carrier, hereinafter also referred to as electronic package insert, can be
15 adjusted to control the dispensing means. In this embodiment the electronic package insert provides a schedule with times at which dispensing to the user is possible, while programming operations are avoided or at least limited, because with the insertion of the medication pack the apparatus is adjusted by the associated information carrier. The apparatus can be
20 provided with display means for displaying the information on the carrier. In this manner the advantage is obtained that the package insert information can always be consulted, so that a user can safely and reliably deal with the medication. The apparatus may be provided with attention means for drawing the attention of a user, on the basis of the information on
25 the carrier, to the time at which a medication is to be taken from the container means. This not only ensures that the apparatus makes known the medication regimen to the user, but also that an impulse is given to the user to keep to the medication regimen.

In a further preferred embodiment the apparatus comprises an
30 electronic memory for fixing the times at which a medication is taken from

the container means. The apparatus may be provided with input means with which a user can feed to the memory specific information on the medication consumption. The information from such a registration can be used by a treating person to establish how the taking behavior of a user is
5 and to feed it to an electronic patients file. On the basis thereof the medication regimen may be adapted, if required, or other measures can be taken. Furthermore, a registration, which is anonymous, may be useful for research. It is advantageous if the apparatus can be connected with a central computer capable of reading out the electronic memory and
10 programming the dispensing control means.

Such information can also be used to effect a dispensing deviating from a normal medication regimen, for instance in case of a calamity. Such a calamity may, for instance, be "Pill forgotten", "Vomiting", "Diarrhea", "Mechanical failure", "Pill not present" or "Pill lost". In a preferred
15 embodiment the dispensing control means are arranged to receive a code indicating that a medication was not taken in a regular manner, while the dispensing control means are arranged to activate, in response to the code, repeated release and dispensing of a medication dose from the container means. Preferably, the dispensing control means are programmed to
20 dispense, in response to the code, a dose that can deviate from a dose associated with a normal medication regimen. It is, for instance, possible that an increased dose (for instance: two pills) is dispensed. It is also possible that on the basis of the information (for instance, it is not possible to restore the protection through additional medication) the apparatus
25 makes a statement that a physician is to be contacted.

After receipt of a code indicating that a mechanical or electronic failure of the apparatus is present, the apparatus can carry out a system test in which a cause of the failure can be traced and restored. The apparatus can make a statement according to which the user is instructed
30 to carry out specific operations or to present the apparatus for repair.

In special embodiments the apparatus according to the invention may be provided with specific additional information; thus it is conceivable that the apparatus may be previously loaded with a medical profile of a user. Data such as age, sex, weight etc. can be previously fed to the apparatus, so that by means of the electronic package insert the medication regimen can be simply determined by the computer program of the apparatus, in principle without the intervention of the user. It is possible that the system is "self learning", in other words that the medication regimen is adapted on the basis of the taking behavior of the user. Such systems offer the advantage that the dose can be very specifically adjusted to a user. Because in the system it is exactly known what the doses taken are, excess doses can be prevented. In this manner a saving of costs is obtained, and the medication prescriptions are improved. In specific embodiments it is conceivable that the user is to answer a number of choice questions included in the information from the carrier, on the basis of which the adjustment can then be carried out automatically. It is also possible that, if required with an authorization appropriate for the purpose, the adjustments can be adapted manually, or if required via an external connection, so that the apparatus can be adjusted completely as desired. In the latter case the operator of the apparatus will have to possess the expertise required for the purpose, in other words will have to be a treating person/a medically trained person.

The invention further relates to a medication package for packaging medication, while the medication package includes an electronically readable carrier with information on the nature and the use of the medication, which medication package and carrier can be included in an apparatus as described above. The carrier need not be firmly connected with the medication package; it is, for instance, conceivable that the carrier and the medication package are presented to the user as one whole, but that for inserting the whole the package is to be inserted separately from the

carrier. Preferably, however, the carrier is firmly connected with the medication package, to increase user-friendliness.

The carrier may comprise an electronic memory, such as, for instance, a microchip. The package insert information may be provided on this chip, which information can be read out by the reading means of the apparatus. It is also conceivable that the carrier only contains an identification code, for instance an optically readable code or a code provided on a magnetic strip. By means of this identification code the medication and the associated medication regimen can be identified from a separate database. The data from such a database can be included in an electronic memory in the apparatus or can be taken from an external source, such as an external PC or the Internet.

The provision of a medication package with an electronically readable carrier according to the invention not only gives the above-mentioned advantages during use, but also considerable advantages during the packaging process. If, for instance, the selected carrier is a microchip, the required information in this microchip can be inputted during the packaging process in a single programming step. The control of this step is more accurate and more reliable than is, for instance, possible when a package insert drafted in the proper language is inserted in the medication package.

In the foregoing, an apparatus for dispensing medication has been discussed. In this connection medication is understood to mean all the pharmaceutical products that can be administered to a user. This also includes nutritious supplements, such as vitamins, but also, for instance, serums, vaccines, blood or blood derivatives. The substances may be in tablet form, but also in the form of capsules, coated tablets, pills, liquid drops, parenteral forms of administration, inhalation substances or sprays. The apparatus may further comprise special provisions for administering the substances, such as a hypodermic needle or inhalator.

Further advantages and features of the invention will be explained in more detail with reference to the drawings, in which:

Fig. 1 shows a disk-shaped medication cassette for an apparatus according to the invention;

5 Fig. 2 shows the interior of the apparatus of Fig. 1, in which a medication cassette is received;

Fig. 3 shows an apparatus according to the invention, in which the cassette of Figs. 1 and 2 can be placed;

10 Fig. 4 shows an alternative embodiment of a medication cassette according to the invention;

Fig. 5 shows the interior of an apparatus, in which a medication cassette of Fig. 4 is received;

Fig. 6 shows the apparatus of Fig. 5;

15 Fig. 7 shows another alternative embodiment of a medication cassette according to the invention;

Fig. 8 shows the apparatus of Fig. 7;

Fig. 9 diagrammatically shows the operation of the apparatus according to the invention;

20 Fig. 10 diagrammatically shows the functional structure of the apparatus according to the invention; and

Fig. 11 shows a partially elaborated block diagram of the program functions in a one-phase contraconceptive pill dispenser.

The medication cassette A shown in Fig. 1 consists of a flat disk 1 with one or more concentrically located annular compartment rows 2
25 thereon. The compartments 3 of the rows 2 always contain one medication tablet 4 and are closed at the bottom by a foil (not shown) that can be pushed through. The compartments 3 of the respective rows 2 are located in a slightly staggered position relative to each other. The circular inner part 5 within the compartment rows 2 contains, in the center, an opening 6
30 flattened on one side 7. On the inner part 5 a row with positioning holes 8

provided beside the compartment rows 2 extends over the whole circle range of the disk 1. Three annular contact strips 10 extend over the whole circle range of the disk beside the positioning holes 8. The contact strips 10 are connected with a microchip 9 located in a recessed position (shown by the dotted line) on the inner part 5. The microchip 9 is loaded with information on the nature and the use of the medication 4 included in the compartments 3.

The medication cassette A can be inserted in a dosing device B, a part of the interior of which is shown in Fig. 2. This part consists of a lid 11, in which is supported a rotatable shaft 12 communicating with a motor 13. Placed on the shaft 12 is the medication cassette A. The rotatable shaft 12 has a form corresponding to that of the central opening 6 of the medication cassette A, so that a rotation of the shaft 12 results in a rotation of the cassette A. Through the optical member 14 the medication cassette A is accurately positioned by means of the positioning holes 8. Beside the optical member 14 are provided sliding contacts 14a engaging the annular contact strips 10, so that an electronic unit (not shown) can read out the chip 9 in the operative condition. The motor 13 is controlled by the electronic unit in cooperation with an optical member 14. As shown in Fig. 3, a key 15 can be pressed by a user on the exterior of the apparatus B. The key 15 extends through the top 16 and engages the compartment rows 2. At the bottom the key 15 has a projecting part (not shown) located in the respective range of the compartment rows 2. The projection is of such design that always only one compartment 3 can be pressed out of a compartment row 2. If a compartment 3 is emptied, the medication cassette A can be rotated by the motor 13 through the desired angle, so that a newly filled compartment is present at the key 15.

Fig. 3 shows a top view of the apparatus B. Disposed at the top 16 are operating keys 17, 18 and a display 19. The operating keys 17 are the known selection arrow keys with which a specific selection can be made

from a program menu; the operating key 18 is the key known as the affirmation key.

The medication cassette A' shown in Fig. 4 consists of three adjoining round tubes 40 in which tablets can be received. The tubes 40 are emptied
5 by elastic springs 41 which can press on tablets, so that always one tablet is positioned before the ejection openings 42. Disposed on the side of the cassette A' is a microchip 43. The microchip 43 is loaded with information on the nature and the use of the tablets 4 which can be received in the tubes 40. The medication cassette A' can be inserted in a dosing device B', a part
10 of the interior of which is shown in Fig. 5. This part consists of the key 44 pressed by a user on the exterior of the apparatus B'. The key 44 communicates with cylindrical ejector pins 45. The ejector pins 45 can be rotated via a gear transmission. By rotating the ejector pins 45 an ejector pin can be positioned before an ejection opening 42, so that ejection of a
15 tablet from a tube 40 becomes possible. Subsequently, the ejector pins 45 can be rotated further, so that none of the ejector pins 45 is positioned before an ejection opening 42. The ejection of a tablet is thus made impossible. Fig. 6 is a top view of the apparatus B'. Disposed at the top 46 are operating keys 47, 48 and a display 49. The operating keys 47 are the
20 known selection arrow keys with which a specific selection can be made from a program menu; the operating key 48 is the affirmation key. The medication cassette A" shown in Fig. 7 comprises a coiled tape 50 on which tablets 51 are disposed in a blister pack. The tape 50 is transported by a rotatable cylinder 52 engaging the tape 50 near the passage 53. Disposed on
25 the side of the cassette A" is, again, a microchip 54. The microchip 54 is loaded with information on the nature and the use of the tablets 51 provided on the tape 50. The medication cassette A" can be coupled to a dosing device B", as shown in Fig. 8. The apparatus B' again comprises operating keys 55, 56 and a display 57; by means of key 58 a tablet 51 can
30 be pushed out of the blister pack.

The operation of the apparatus will be described with reference to Fig. 9 and the apparatus shown in Figs. 1-3. The steps indicated by a broken line have a facultative character. A filled cassette A is placed by a user in the apparatus B, after which the lid 11 is closed. The motor 13 positions the cassette A such that one compartment 3 lies under the key 15. Sliding contacts make contact with the strips 40, so that the electronic unit of the apparatus B can read out the chip 9 on the cassette A. Depending on the type of medication and the associated information contained on the chip, additional information can be fed by the user. The information can be fed in the form of multiple choice questions which can be answered by the user by operating the keys 17 and 18. These questions are dependent on the type of medication contained in the cassette and are for additional information to cause the unit to compute the desired time at which a medication can be taken out. When the dispensing time has come, the motor rotates a compartment before the key, and an attention signal is given. The user reacts to the signal by pressing the key 15. Thus a medication tablet is released. By operating the key 15 a switch 15a is activated. By activating this switch 15a, the unit registers in an electronic memory the time at which the medication is taken out. If desired, additional information is interactively fed to the electronic unit. Such information can relate to a reason for which the recommended medication regimen was deviated from (for instance: vomiting or the like). The information is stored in the memory, along with the dispensing time, and can be read out later by an authorized person and be added, if required, to an electronic patients file.

The user can at all times consult the package insert by means of the operating keys. The package insert information can be displayed as is conventional for a traditional paper package insert text, but can also be displayed in an interactive program menu. By means of the information inputted at the dispensing times the unit can display on the display 19

special user instructions, such as: "cassette nearly empty", "replace cassette", "shelf life term expired", "take 2 tablets" or "consult physician".

The registration thus built up in the apparatus, during which the dispensing times are fixed, if required provided with additional information, can be analyzed by a treating person. On the basis thereof the medication regimen can be adapted, if required, or other measures can be taken. To this end, the treating person connects the apparatus with a central computer, which can read out the electronic memory, and which can program the dispensing control means. The registration is coupled with an electronic patients file available at the treating person. This person can carry out a number of statistical analyses on this registration, such as the determination of the average duration between two taking times. On the basis thereof the treating person can form a picture of the desired medication regimen and carry out adaptations therefor in the computer program of the apparatus, by adjusting the apparatus by means of the required authorization.

Fig. 10 diagrammatically shows the functional structure of the apparatus according to the invention. The control unit 60 is the central electronic unit determining the functionality of the apparatus. The unit 60 is provided with a RAM memory 61, a ROM memory 62, a CPU 63 and a timer 64. The unit 60 is fed by two 1.5 V batteries 65, which provide the power supply for at least one year. To be able to warn the user in time that the battery 65 runs down, the unit 60 comprises a battery detection circuit 66. The unit 60 is further connected via a keyboard interface 67 with a keyboard 68 and via an LCD display driver 69 with an LCD display 70. The unit 60 controls an alarm 71 and, on the basis of a position detection 72, a motor 73. The electronic unit is further fed by data from an electronic readable carrier in the form of an EEPROM 74 provided on a medication package 75.

Fig. 11 shows a partially elaborated block diagram of the program functions in a one-phase contraconceptive pill dispenser. It should be noted that the medical correctness of the diagram is not important. The number of functions displayed is limited. The example of Fig. 11 is only for the purpose of explaining possible functions which an electronic package insert can have according to the invention. The program opens with a Welcome screen 76, from which a number of screens can be activated. These displays can be a Set-up screen 77, a Start menu screen 78, a Help menu screen 79 and a User menu screen 80 (set up as standard).

10 In the Set-up screen 77 general data can be filled in, serving to set up the one-phase contraceptive pill dispenser. Such data relate to, inter alia, the present date/time, the name of the user, birth date, telephone of physician, preferred time for taking the pill, alert set-ups (for instance: sound intensity, vibrational alert), preferred use of the pill (for instance: 15 swallowing or a stop week).

In the Start menu screen 78 a start date can be inputted. This start date can be determined on the basis of the pill last taken or on the first day of the last menstruation. The dispenser gives a recommended date, which may be adapted, if required.

20 In the Help menu screen 79 general information on the pill consumption can be found in a number of subscreens 81. By answering questions the information can also be given more specifically, as shown, for instance, at the item Pregnancy 82. When answering the question: "are you pregnant?", the advice can be given via a yes/no answer to stop the pill 25 consumption or to make a test or to consult a physician.

The Consumption menu screen 80 has a number of subscreens 83, of which the items Calamities 84 and Bleedings 85 are elaborated.

Such a calamity may be, for instance, "Pill forgotten" 86, "Vomiting" 87, "Diarrhea" 88 or "Pill lost" 89. The incidents "Vomiting" 87 and 30 "Diarrhea" 88 are elaborated in Fig. 11. It is requested that the date of the

incident be inputted in the dispenser. The dispenser computes whether this occurred more or less than two hours ago after taking the last pill. If it is longer than two hours ago, a statement is given that the incident has no consequence to the contraception; if this is not the case, an extra pill is to be taken and/or the physician is to be consulted. In the incident "Pill lost" 89 it is requested that the date thereof be inputted. A statement is given that the user is to take an extra pill. If this has been done, a statement appears that the protection has been restored again.

The subscreen Bleedings 85 establishes whether the bleeding occurs during a so-called stop week. If this is the case, the statement is given that such a phenomenon is normal and has no consequences to the protection. If the bleeding occurs during the pill consumption, the date thereof is to be inputted. It is established whether the bleeding occurs more or less than four months after the beginning of the pill consumption. In the case of less than four months a statement is given that a bleeding is not unusual and has no consequences to the protection. If the bleeding occurs more than four months after the beginning, the advice is given to consult a physician.

Another calamity to which the apparatus can give a response is "Mechanical failure" or "Pill not present". Such cases cannot be prevented during intensive use, and an important part of the security and possibilities of use of the apparatus is determined by an adequate response to such circumstances. If the apparatus receives a code from which it appears that a medication was not taken in a regular manner through a mechanical or electronic failure of the apparatus, the apparatus carries out a system test in which a cause of the failure can be traced and restored. The apparatus can give a statement according to which the user is instructed to carry out specific operations or to present the apparatus for repair. The apparatus also ensures that the medication prescription is restored again, for instance by dispensing medication according to a prescription deviating from a normal medication regimen (for instance: two pills instead of one). If it

appears from the electronic package insert information that a restoration is not possible, a statement is made that a physician is to be contacted.

The invention is not limited to the exemplary embodiments described with reference to the drawings, but comprises all kinds of variations thereof, of course as far as falling within the scope of protection of the appended claims. It is pointed out that, although the exemplary embodiments of the application relate to an apparatus with operating keys, the apparatus may also be provided with a complete writing machine keyboard. The apparatus may have all kinds of provisions for making contact with a PC, such as a parallel or serial connection, infrared connection etc. It is further conceivable that the apparatus is suitable for effecting the dispense of medication for several medication prescriptions. This is possible, for instance, because several cassettes can be inserted in the apparatus, each having their specific control and setups, or because a cassette contains a combination therapy.

CLAIMS

1. An apparatus for dispensing medication and for providing information on the nature and the use thereof, comprising:
 - container means suitable for receiving a medication package provided with medication; and
 - 5 - dispensing means for releasing and dispensing medication from the container means;characterized in that
 - the container means are further suitable for receiving an electronically readable carrier with information on the nature and the use of the
 - 10 medication, which carrier is included in the medication package; and that the apparatus is further provided with:
 - reading means for reading out information from this carrier.
2. An apparatus according to claim 1, characterized in that it is provided with dispensing control means for controlling the dispensing
- 15 means on the basis of the information on the carrier.
3. An apparatus according to claim 1 or 2, characterized in that the apparatus is provided with input means with which a user can feed to the memory specific information on the medication consumption.
4. An apparatus according to any one of claims 1-3, characterized in
- 20 that the dispensing control means are arranged to receive a code indicating that a medication was not taken in a regular manner; and that the dispensing control means are arranged to activate, in response to the code, repeated release and dispensing of a medication dose from the container means.
- 25 5. An apparatus according to claim 4, characterized in that the dispensing control means are programmed to dispense, in response to the

code, a dose that can deviate from a dose associated with a normal medication regimen.

6. An apparatus according to claims 4-6, characterized in that the apparatus, after receipt of a code indicating that a mechanical or electronic
5 failure of the apparatus is present, carries out a system test in which a cause of the failure can be traced and restored.

7. An apparatus according to any one of the preceding claims, characterized in that it is provided with display means for displaying the information on the carrier.

10 8. An apparatus according to any one of the preceding claims, characterized in that the apparatus is provided with attention means for drawing the attention of a user, on the basis of the information on the carrier, to the time at which a medication is to be taken from the container means.

15 9. An apparatus according to any one of the preceding claims, characterized in that the apparatus comprises an electronic memory for fixing the times at which a medication is taken from the container means.

10. An apparatus according to any one of the preceding claims, characterized in that the apparatus can be connected with a central
20 computer capable of reading out the electronic memory.

11. An apparatus according to any one of the preceding claims, characterized in that the apparatus can be connected with a central computer capable of programming the dispensing control means.

12. A medication package for packaging medication, characterized in that
25 the medication package includes an electronically readable carrier with information on the nature and the use of the medication, which medication package and carrier can be included by an apparatus according to any one of the preceding claims.

13. A medication package according to claim 9, characterized in that the
30 carrier is firmly connected with the medication package.

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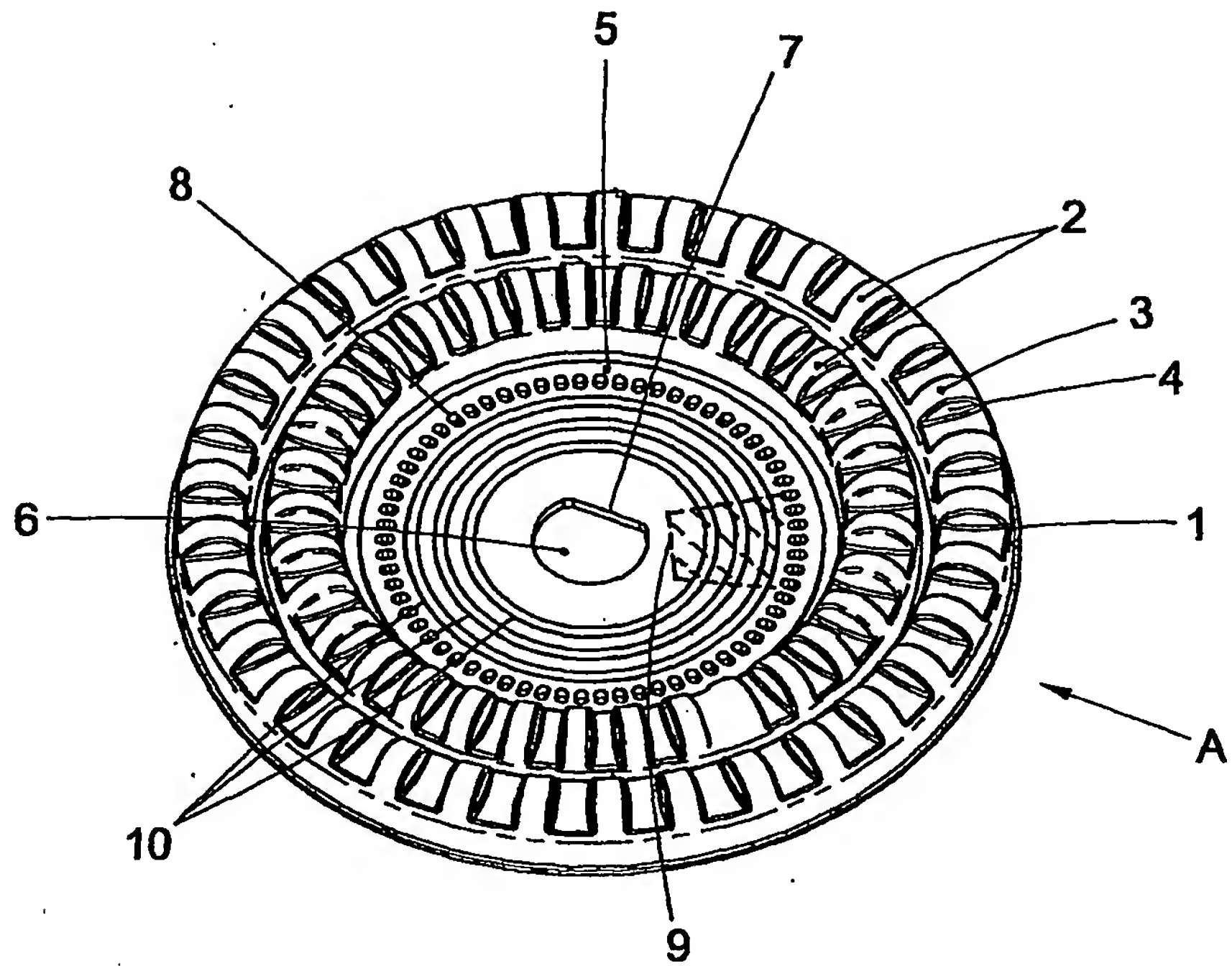


Fig. 1

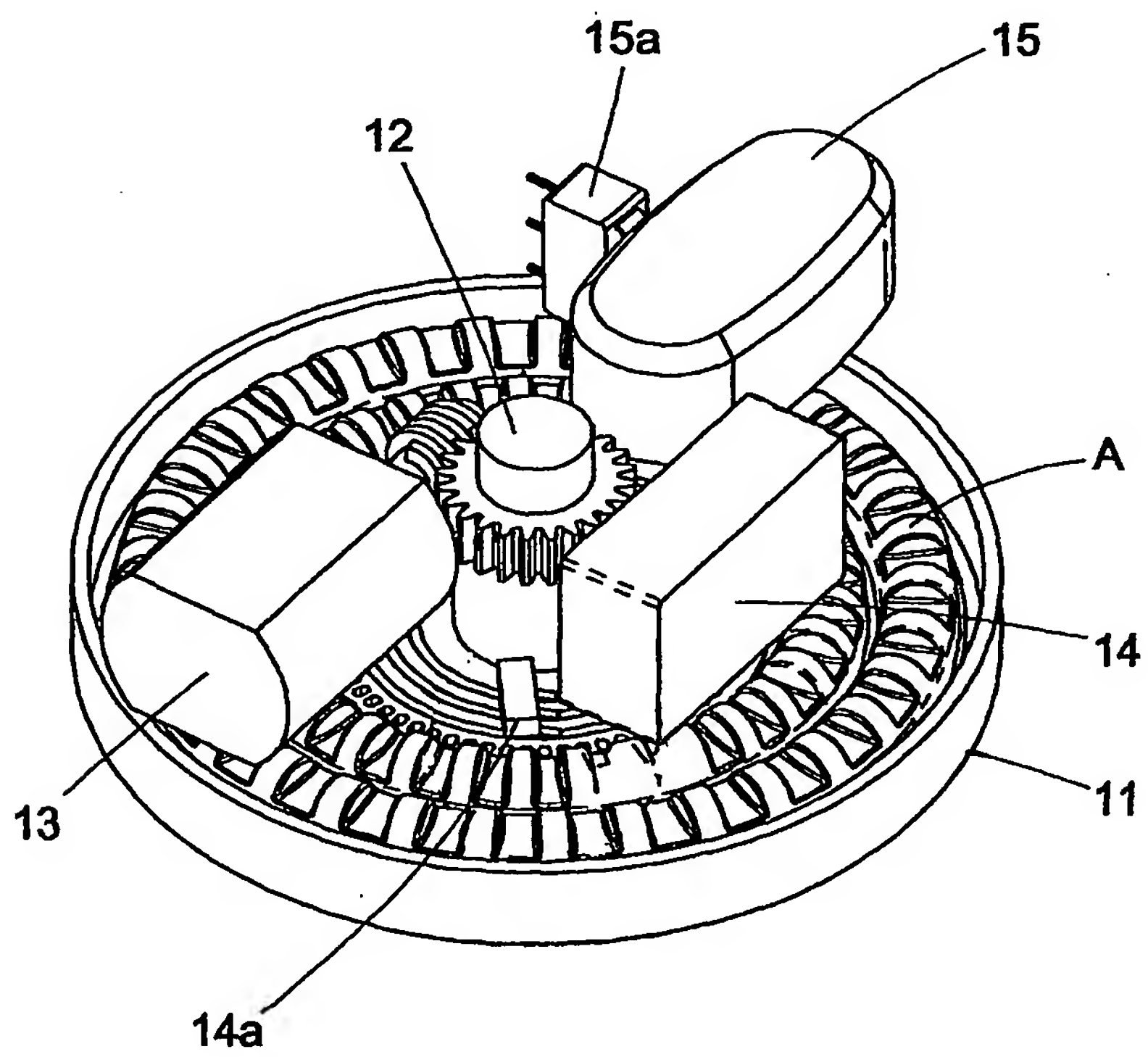


Fig. 2

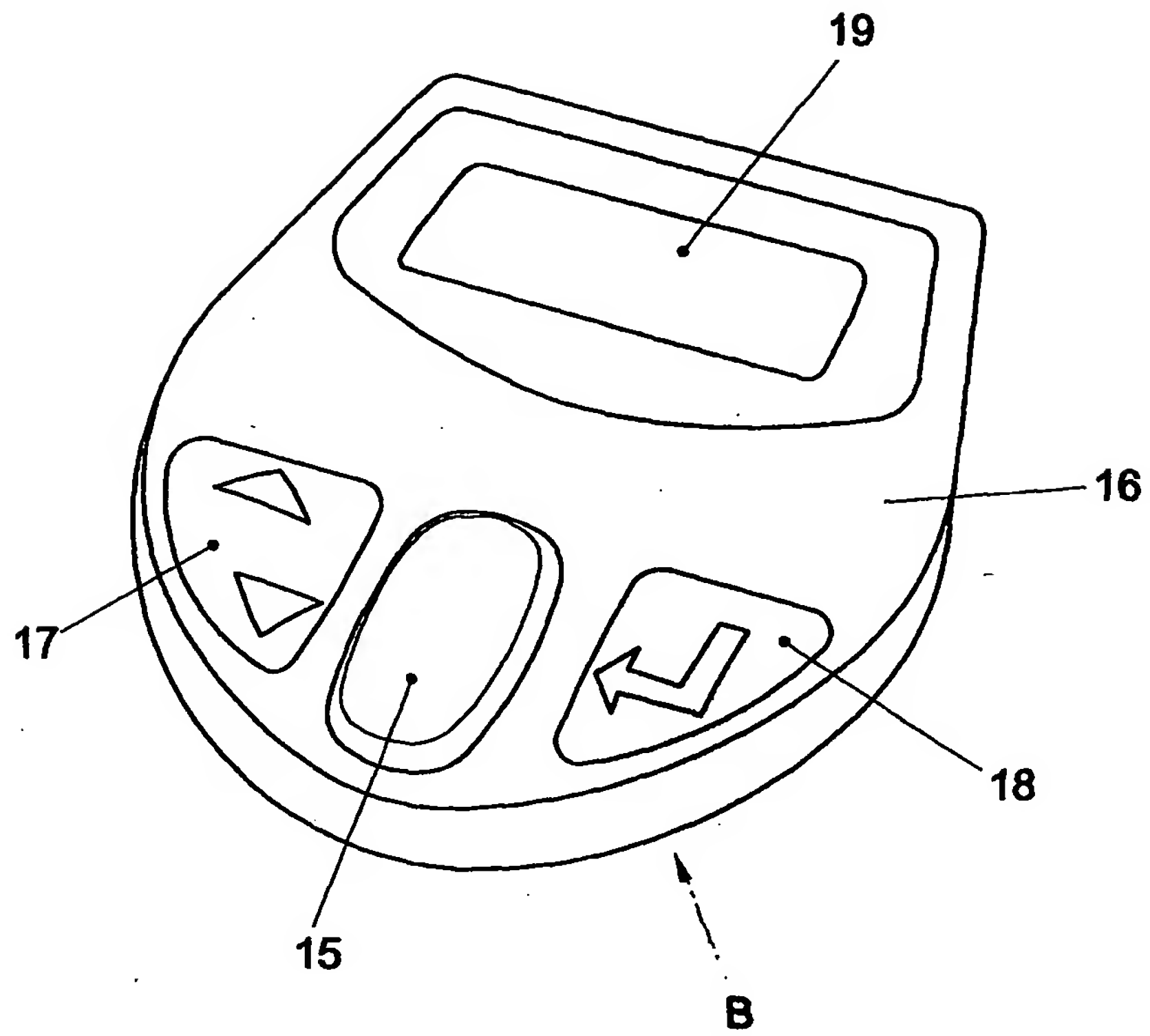


Fig. 3

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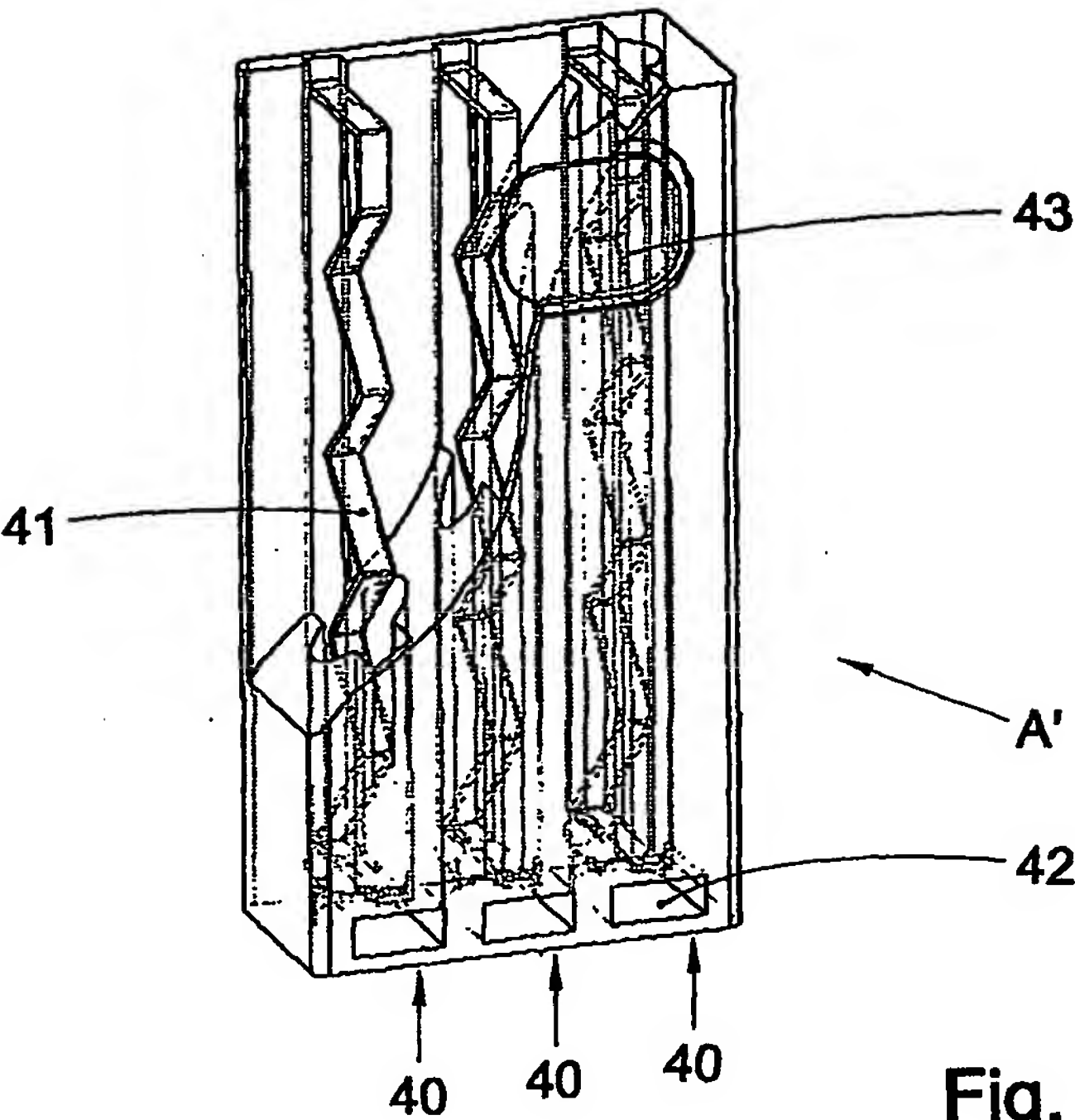


Fig. 4

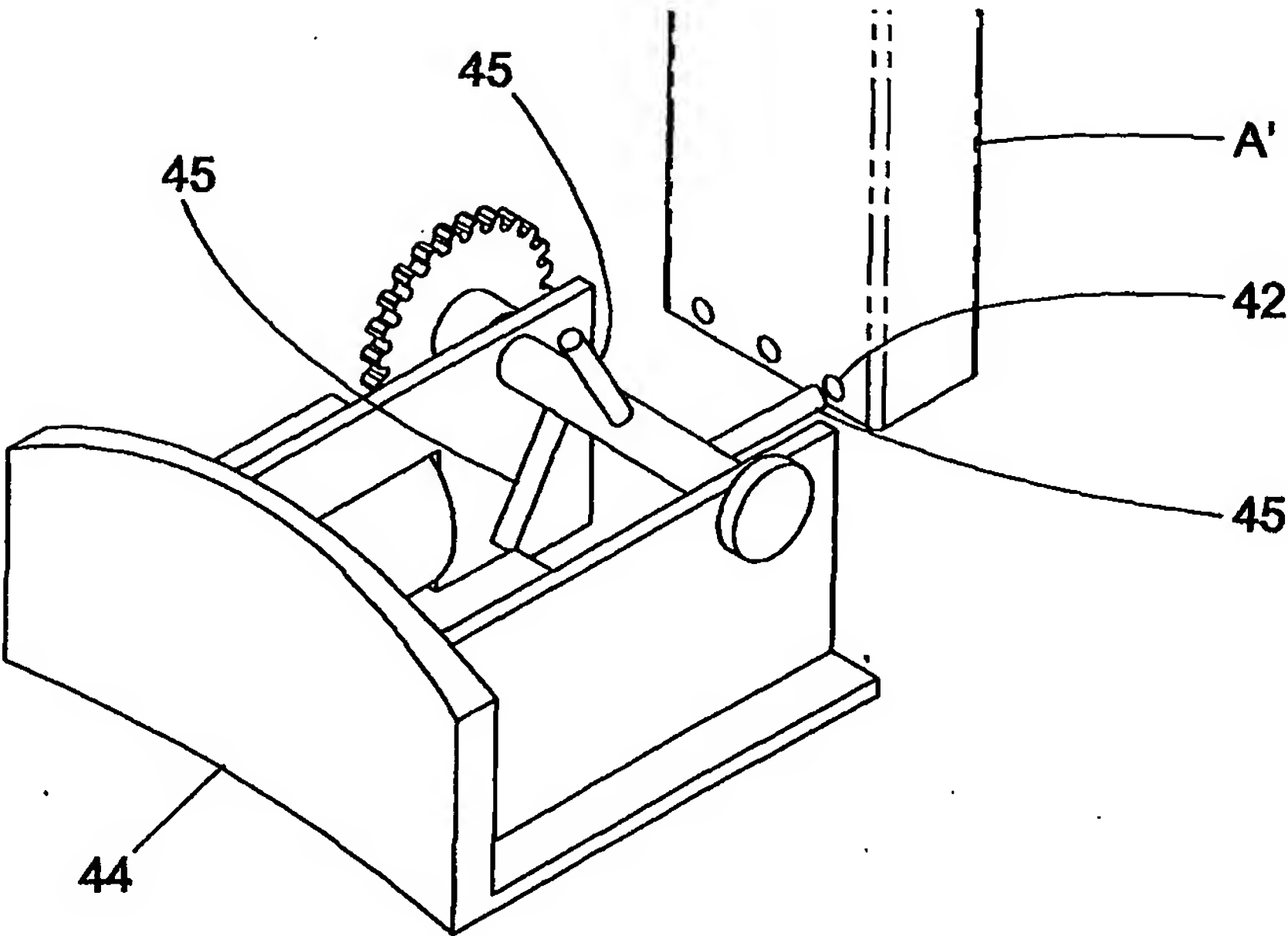


Fig. 5

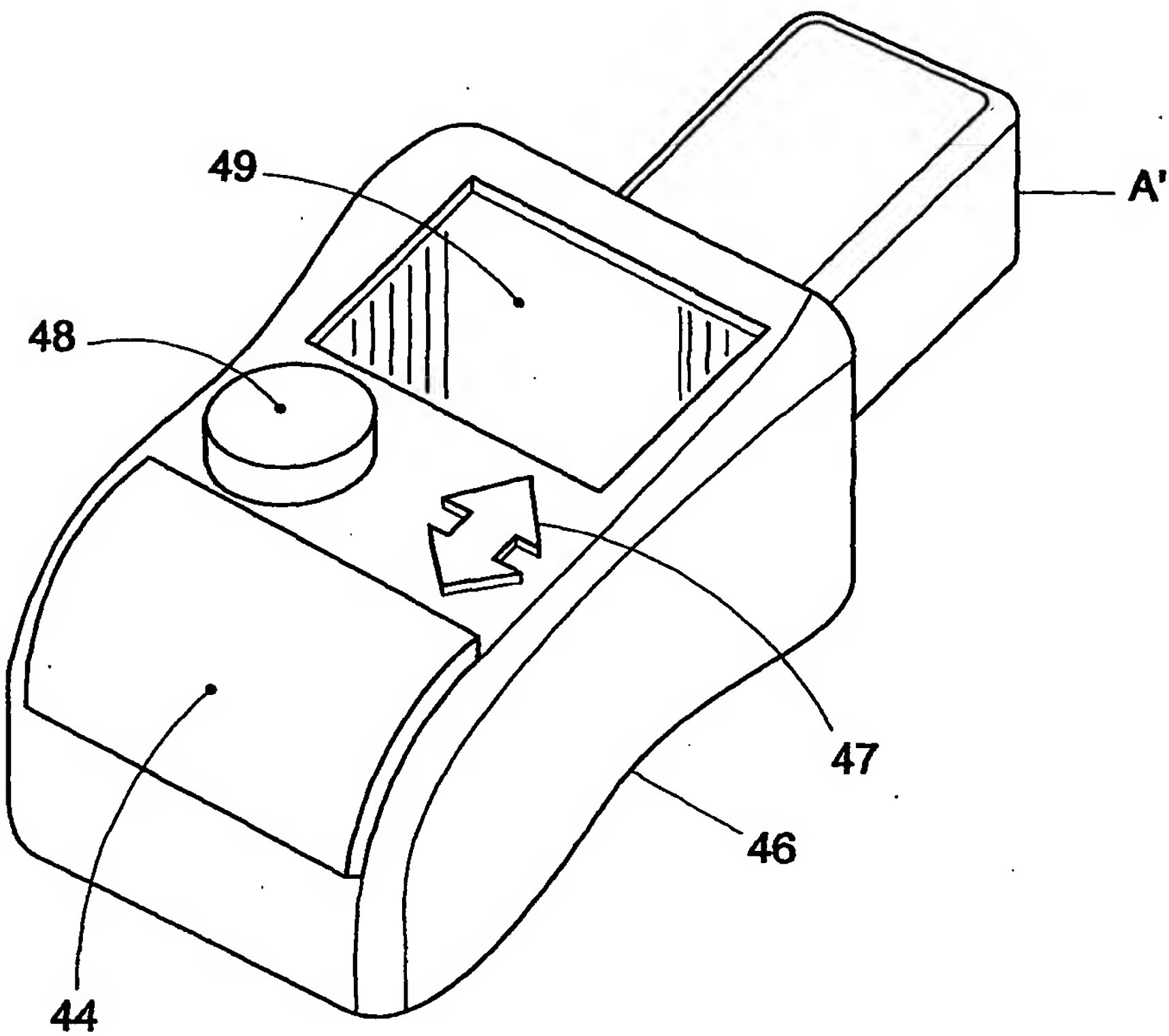


Fig. 6

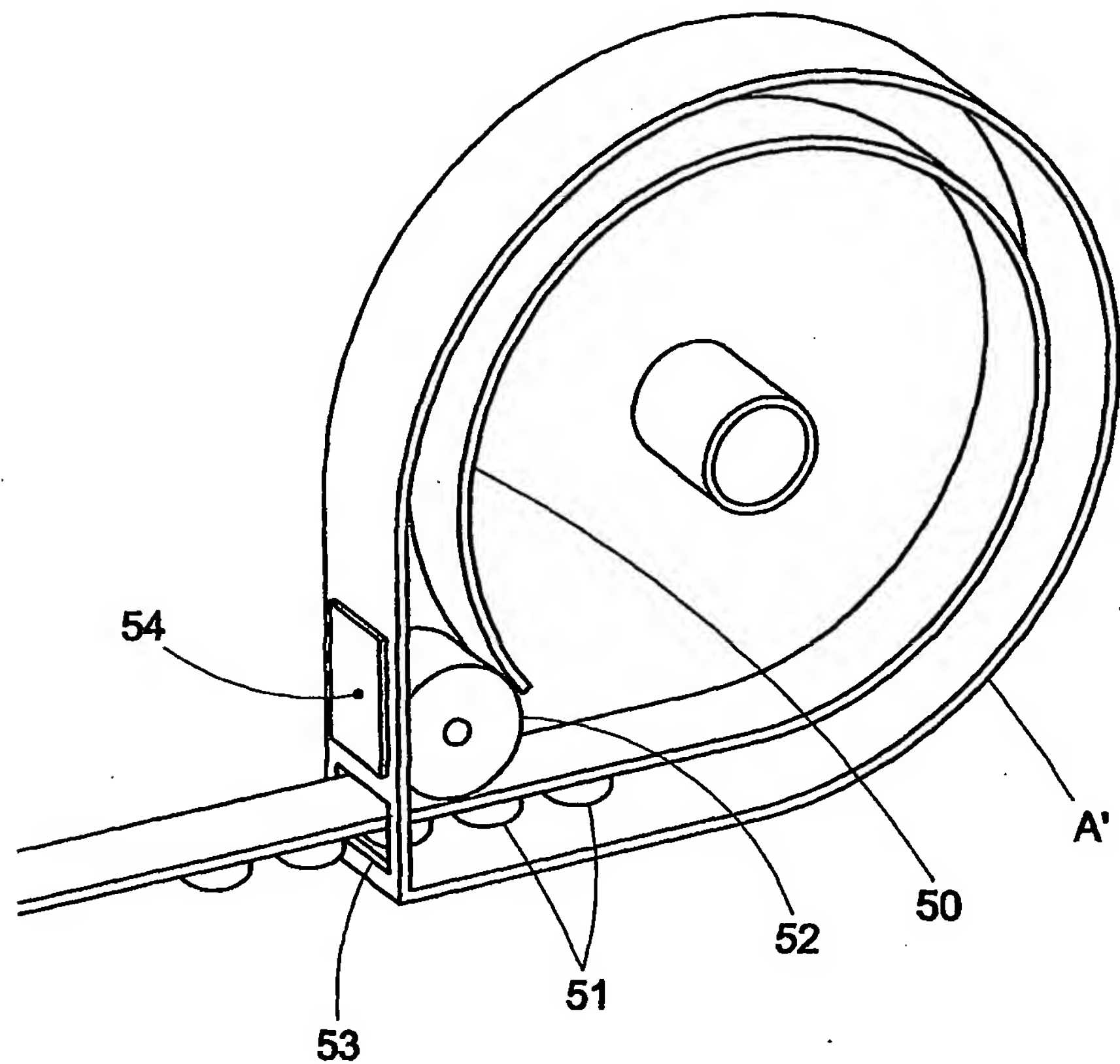


Fig. 7

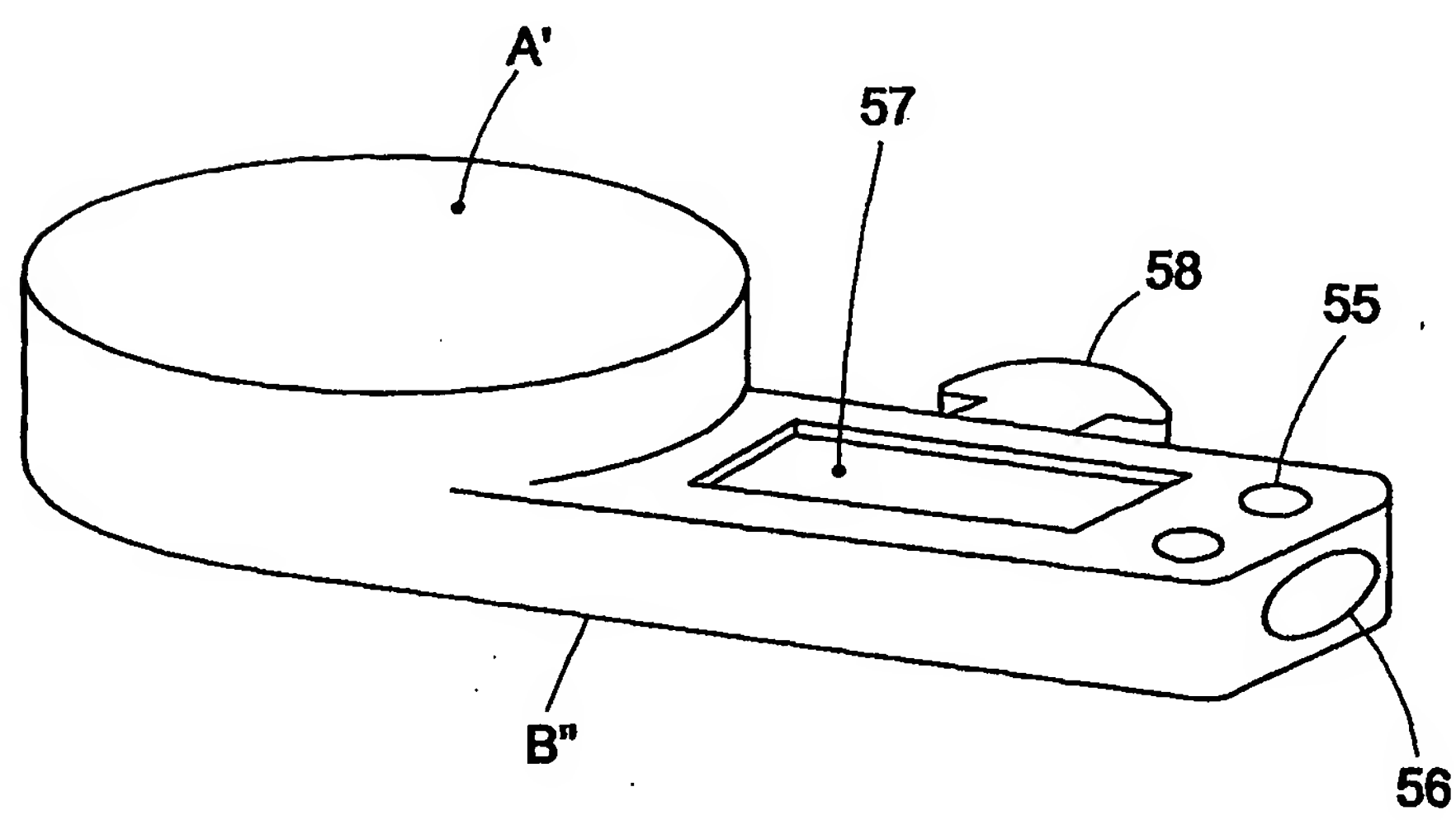


Fig. 8

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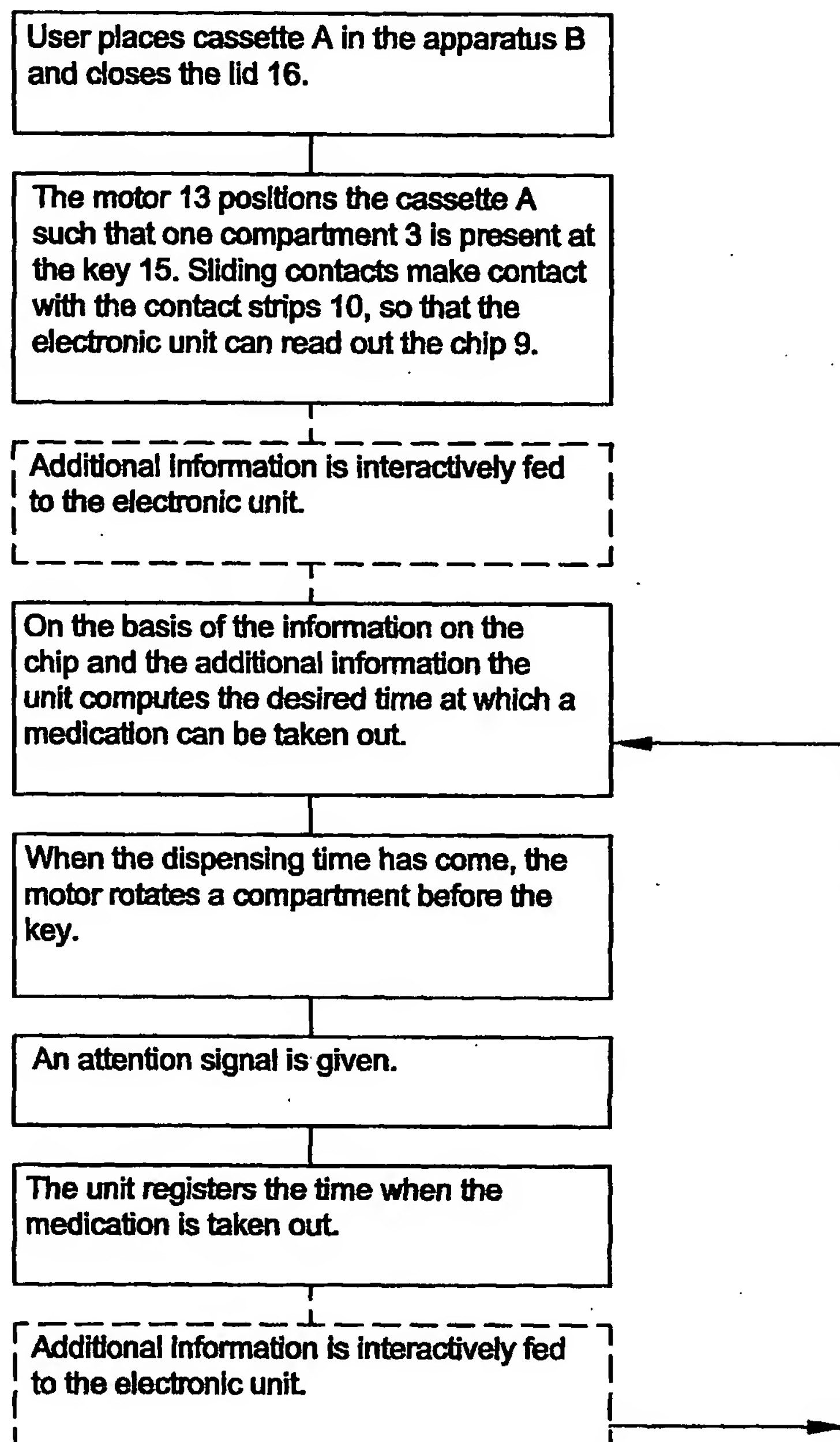


Fig. 9

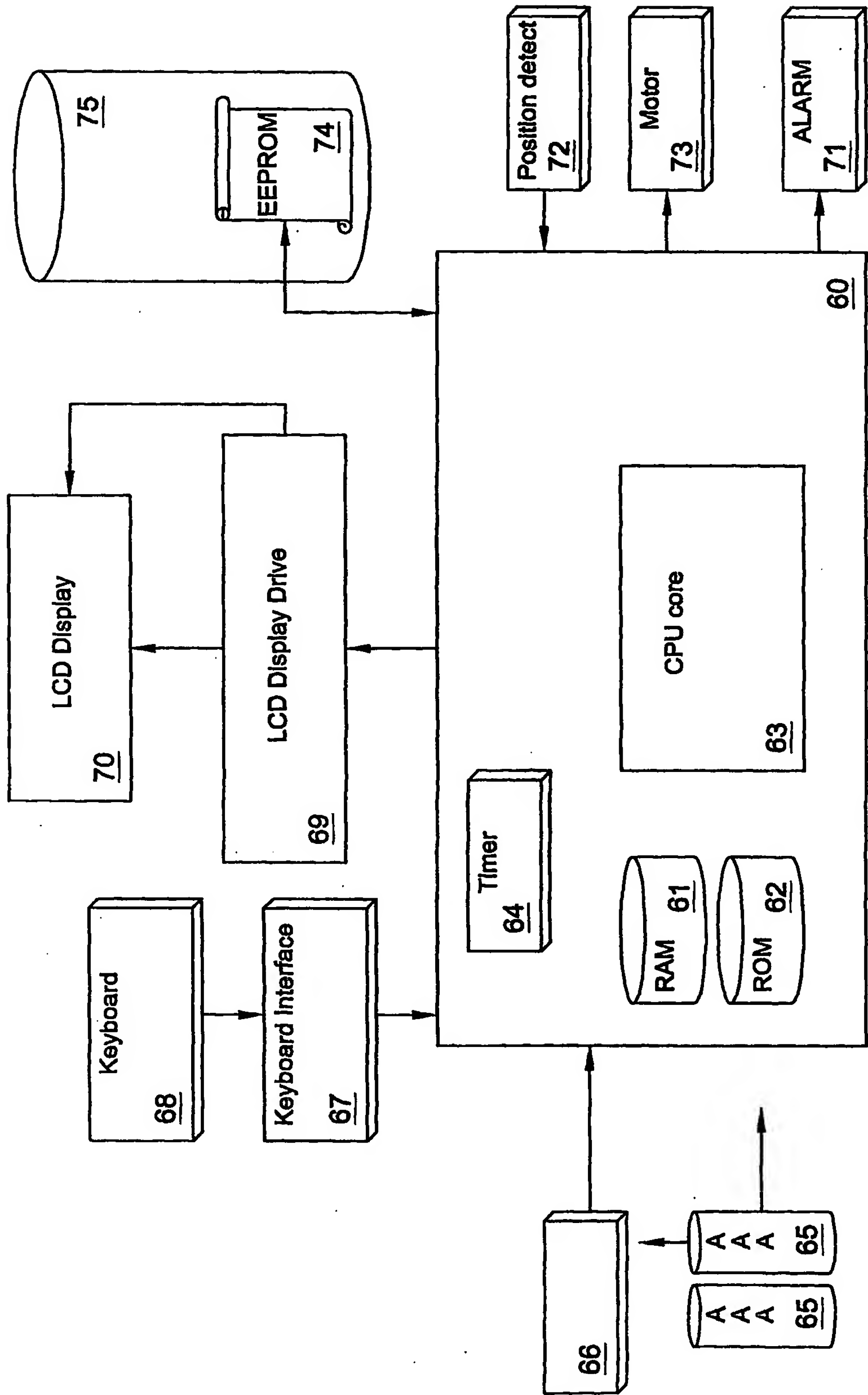
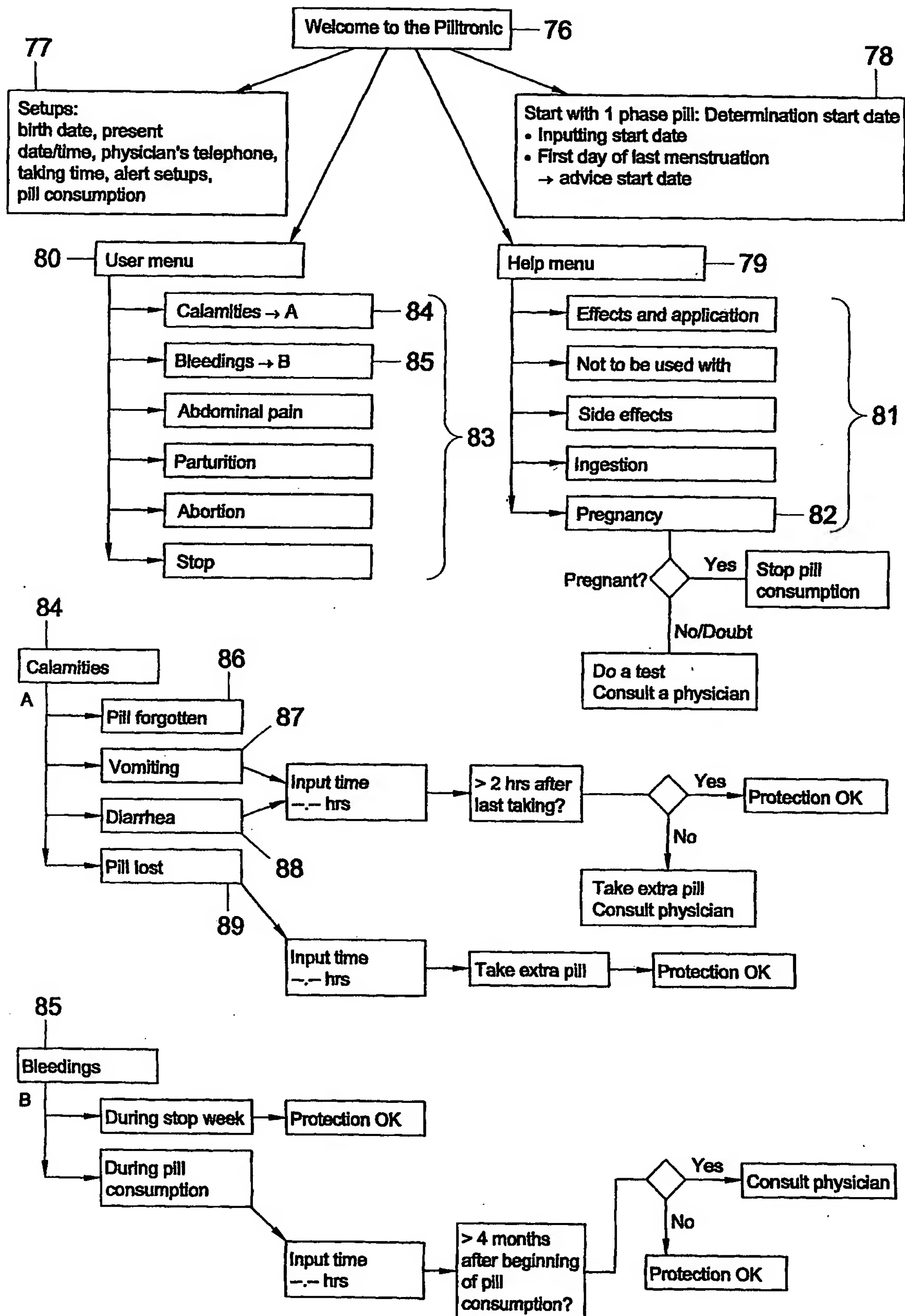


Fig. 10

Fig. 11



INTERNATIONAL SEARCH REPORT

b 1al Application No

PCT/NL 01/00417

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61J7/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61J

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00 25720 A (HUERGA CARLOS DE) 11 May 2000 (2000-05-11) abstract	1-3,7-13
Y	page 8, line 23 -page 9, line 6; figures	4-6
X	EP 0 827 731 A (BIOSTAT) 11 March 1998 (1998-03-11) abstract	1-3,7-13
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Further documents are listed in the continuation of box C.



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Date of the actual completion of the international search

3 October 2001

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
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